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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jeffrey L. Cleland, Amy Lim and Michael Frank Powell

Assignee: Genentech, Inc.

Title: COMPOSITIONS FOR MICROENCAPSULATION OF ANTIGENS FOR USE AS VACCINES

Serial No.: 08/846,933

Filing Date: April 30, 1997

Examiner: Hines, J.

Art Unit: 1645

Docket No.: M-9169-3C US

COMMISSIONER FOR PATENTS
Washington, D. C. 20231

PETITION FOR WITHDRAWAL OF FINALITY OF OFFICE ACTION

UNDER 37 C.F.R. § 1.181 (M.P.E.P. § 706.07(c))

Dear Sir:

In response to the Final Office Action dated October 19, 2000 in the above-referenced application, Applicants respectfully request reconsideration of the finality of the Office Action.

The present application is a continued prosecution application ("CPA") of the parent application. The Final Office Action was the first Office Action in this CPA application. M.P.E.P. § 706.07(b) identifies those situations in which the claims of a new application may properly be finally rejected in a first Office Action. Section 706.07(b) states that such a rejection is proper only when:

[A]ll claims of the new application . . . would have been properly finally rejected *on the grounds and art of record* in the next Office action if they had been entered in the earlier application.

(Emphasis added.) Applicants substantially amended the claims of the present application in a Preliminary Amendment filed on August 7, 2000 (copy attached), before the issuance of the Final Office Action. As is clear from the Final Office Action, the claim amendments in the Preliminary Amendment removed a number of rejections under 35 U.S.C. § 112 that were

outstanding at the close of prosecution in the parent case. In particular, the § 112, first paragraph rejections based on the phrases “beginning at the completion of,” “1 milliliter of aqueous antigen per 3 gram of polymer or less,” and “about 1 to 2 days” were overcome in the Preliminary Amendment. Thus, all claims of the new application would *not* have been properly finally rejected on the grounds of record in the parent case. The amended claims overcame some of the outstanding rejections, failed to overcome some of the outstanding rejections, and prompted the Examiner to make an additional rejection.

In light of this record, Applicants respectfully submit that the Preliminary Amendment clearly raised new issues for consideration by the Examiner. As stated in M.P.E.P. § 706.07(b):

[I]t would not be proper to make final a first Office action in a continuing . . . application where the application contains material which was presented in the earlier application after final rejection or closing of prosecution but was denied entry because (A) *new issues were raised that required further consideration* and/or search, or (B) *the issue of new matter was raised*.

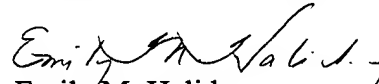
The parent application was under final rejection when Applicants filed the present CPA, followed by the Preliminary Amendment. Applicants chose to file a CPA and amend the claims via Preliminary Amendment, rather than attempt to file the claim amendments after final rejection in the parent case. Applicants deliberately elected this strategy because the amendments to the claims were sufficiently substantial that Applicants believe that the Patent Office would refuse entry of the amendments after final rejection on the ground that the amendments raised new issues that required further consideration. This belief was based on well-established Patent Office practice. M.P.E.P. § 714.13. In effect, Applicants have been penalized with a Final Office Action, which severely limits Applicants’ options in prosecuting the application, because Applicants did not engage in the likely futile exercise of filing amendments after final rejection in the parent case.

In support of Applicants’ contention that these amendments would not have been entered in the parent case, Applicants point out that Claims 1, 4-9, and 23-27 were rejected in the Final Office Action under 35 U.S.C. §112, first paragraph because the Examiner believed that the reference in Claim 1 to “individual microspheres” was not supported in the specification. Although the rejection was made under § 112, the Examiner’s rationale indicates that the issue is essentially one of whether the phrase “individual microspheres” constitutes new matter. For this additional reason, the record establishes that,

had the amendments set forth in the Preliminary Amendment been filed after final rejection in the parent case, these amendments would not have been entered.

Thus, Applicants submit that the final rejection is premature and, in effect, deprives Applicants of the examination for which they paid when the CPA was filed. Fairness, as well as the M.P.E.P., dictates that the finality of the outstanding Office Action be withdrawn. Applicants therefore respectfully petition for such withdrawal. The transmittal accompanying this Petition contains an authorization to charge any required fees, or to credit any overpayment(s) to Deposit Account No. 19-2386. If there are any questions regarding this Petition, the Patent Office is invited to telephone the undersigned at (408) 487-1296.

Respectfully submitted,


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